

**REMARKS/ARGUMENTS**

Claims 2-18, 21-36, 39-49 and 51-54 are under examination. Claim 51 is independent. Claim 51 (from which claims 2-18, 21-36, and 52-54 depend) is directed to an apparatus. Claim 54 (from which claims 39-49 depend) is directed to a method.

*The device of claim 51 is novel and nonobvious*

Claim 51 was rejected as anticipated by Ramsey *et al.* or by Blankenstein *et al.*, and claims dependent from claim 51 were rejected as obvious in view of Ramsey *et al.* or Blankenstein *et al.* either singly or in combination with secondary references. It is axiomatic that if it is established that independent claim 51 is novel and nonobvious in view of both of Ramsey *et al.* and Blankenstein *et al.*, the dependent claims are also novel and nonobvious.

As previously pending, Claim 51 recited:

... (c) a flow control system responsive to the detection apparatus, and adapted to direct biological material into a selected branch channel and to reverse, the direction of movement of biological material that has been directed into a selected branch channel.

In rejecting this claim the Office stated:

"Regarding the limitation that *the device* be 'adapted . . . to reverse the direction of movement of biological material [ . . . ]', the Examiner considers this limitation to be directed to an intended use of the device." (emphasis added)

However, claim 51 did not require that the *device* be adapted to reverse flow. Rather, the *flow control system* is adapted to reverse the direction of flow in response to a signal from the *detection apparatus*, a feature not described or suggested in the Ramsey *et al.* or by Blankenstein *et al.* references. To more clearly characterize this aspect of invention and more clearly set forth the relationship of the components of the system, claim 51 has been amended to read as follows:

51. *(as amended)* A microfluidic system for processing a flow of biological material in a fluid, wherein said system comprises (i) a substrate having an analysis unit microfabricated thereon, (ii) a detection apparatus, (iii) a processor, (iv) and a flow control system:

- wherein said analysis unit comprises
  - (a) a main channel in communication with a sample inlet,
  - (b) a detection region downstream of the sample inlet,
  - (c) a branch point discrimination region adjacent to and downstream of the detection region; and
  - (d) at least two branch channels originating at the branch point discrimination region and in communication with the main channel;
- wherein said detection region comprises a detection apparatus for evaluating the biological material according to at least one characteristic as the material passes through the detection region;
- wherein said processor is configured to receive a signal from the detection apparatus, execute an algorithm based on the signal, and actuate the flow control system to reverse the flow of fluid in a branch channel; and
- wherein said flow control system is responsive to the processor and is adapted to direct biological material into a selected branch channel and to reverse the direction of movement of biological material that has been directed into a selected branch channel.

Support for this amendment is replete in the specification, including in at least paragraphs [0046], [0051], [0072], [0079]-[0082], [0092]-[0094], [0097], [0127] and [0145]. Neither of the references cited by the Office described or suggested a system in which the direction of flow is reversed in response to a signal from the detection apparatus. As discussed below, neither of the references cited by the Office described or suggested a system including a processor configured to receive a signal from the detection apparatus, execute an algorithm based on the signal, and

actuate the flow control system to reverse the flow of fluid in a channel.

Blankenstein

Using the device of the Blankenstein *et al.* reference, fluid can be flowed in the reverse direction of normal operation to empty the contents of syringe pumps through three-way valves into a waste container. However, the Blankenstein *et al.* device did not include a processor configured to receive a signal from the detection apparatus, execute an algorithm based on the signal, and actuate the flow control system to reverse the flow of fluid in a channel.

Ramsey

Ramsey *et al.* described a microchip channel in which an electric field is used to spatially focus material traversing the material transport channel. At col. 5, lines 1-5, Ramsey *et al.* noted that if the potential at the channel intersection defining the focusing chamber is adjusted so that it exceeds the potential applied to the sample reservoir (an adjustment not made in the normal operation of the device) the direction of transport in the sample channel reverses. However, the Ramsey *et al.* device did not include a processor configured to receive a signal from the detection apparatus, execute an algorithm based on the signal, and actuate the flow control system to reverse the flow of fluid in a channel.

***The method of claim 54 is novel and nonobvious***

Claim 54 depends from claim 51, and is therefore patentable for the reasons described above. Moreover, claim 54 as amended is directed to a method for sorting cells that includes the steps of directing at least one cell out of a selected branch channel so that it passes through the detection region a second time. This method is not described or suggested in the Ramsey *et al.* or Blankenstein *et al.* references cited by the Office.

***The claims are in condition for allowance***

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is

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respectfully requested.

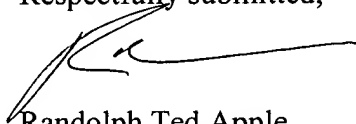
***Information Disclosure Statement***

Copies of references 0066-0076 and 0078-0099 of the IDS submitted 7 April 2005 are enclosed, as requested by the Examiner in paragraph 1 of the Office Action.

**CONCLUSION**

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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